IN THE CLAIMS

Please substitute pending claims 6-10, 12-16, 18 and 20 with the corresponding amended claims, as shown below:

6. (Amended) The method of claim 1, wherein the method results in a steady-state testosterone 24-hour pharmacokinetics profile in the male subject, wherein the profile exhibits a first testosterone serum concentration upon administration of the composition and exhibits a second testosterone serum concentration having a small increase compared to the first testosterone serum concentration at about two hours after application, followed by a decrease to a third testosterone serum concentration that remains relatively constant for the remainder of the day.

7. (Amended) The method of claim 6, wherein the first testosterone serum concentration is between about 400 ng/dL to about 900 ng/dL, the second testosterone serum concentration is between about 500 ng/dL to about 1000 ng/dL , and the third testosterone serum concentration is between about 450 ng/dL to about 950 ng/dL.

8. (Amended) The method of claim 6, wherein the third testosterone serum concentration is between about 300 ng/dL and about 1,000 ng/dL.

9. (Amended) The method of claim 1, wherein the method causes an increased average dihydrotestosterone serum concentration in the male subject compared to the average dihydrotestosterone serum concentration of the male subject before administration of the composition.

10. (Amended) The method of claim 1, wherein the method causes an increase in the bone mineral density of the male subject compared to the bone mineral density of the male subject before administration of the composition.

12. (Amended) The method of claim 1, wherein the method causes increased libido in the male subject compared to the libido of the male subject before administration of the composition.

13. (Amended) The method of claim 1, wherein the method causes improved sexual performance in the male subject compared to the sexual performance of the male subject before administration of the composition.

14. (Amended) The method of claim 13, wherein the improved sexual performance comprises an increase in the percentage of full erection by the male subject compared to the percentage of full erection by the male subject before administration of the composition.

15. (Amended) The method of claim 1, wherein the method causes improved mood in the male subject compared to the mood of the male subject before administration of the composition.

16. (Amended) The method of claim 1, wherein the method causes increased muscle strength in the male subject compared to the muscle strength of the male subject before administration of the composition.

18. (Amended) The method of claim 1, wherein the method causes improved body composition in the male subject compared to the body composition of the male subject before administration of the composition.

20. (Amended) The method of claim 1, wherein the method causes negligible skin irritation.

Please add new claims 146-151

146. (New) A method of transdermally delivering testosterone to a male subject in need thereof, comprising administering to the subject a pharmacologically effective amount of a composition to a selected area of skin of the subject, wherein the composition comprises: testosterone, at least one penetration enhancer and at least one gelling agent; and wherein the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration; and wherein the method results in a steady-state testosterone 24-hour pharmacokinetics profile in the male subject, wherein the profile exhibits a first testosterone serum concentration upon administration of the composition and exhibits a second testosterone serum concentration having a small increase at about two hours after application compared to the first testosterone serum concentration, followed by a decrease to a third testosterone serum concentration that remains relatively constant for the remainder of the day.

147. (New) The method of claim 146, wherein the first testosterone serum concentration is between about 400 ng/dL to about 900 ng/dL, the second testosterone serum concentration is between about 500 ng/dL to about 1000 ng/dL , and the third testosterone serum concentration is between about 450 ng/dL to about 950 ng/dL.

148. (New) The method of claim 146, wherein the first testosterone serum concentration is between about 400 ng/dL to about 1000 ng/dL, the second testosterone serum concentration is between about 400 ng/dL to about 1000 ng/dL , and the third testosterone serum concentration is between about 400 ng/dL to about 1000 ng/dL.

149. (New) The method of claim 146, wherein the first testosterone serum concentration is between about 450 ng/dL to about 900 ng/dL, the second testosterone serum concentration is between about 550 ng/dL to about 1000 ng/dL , and the third testosterone serum concentration is between about 450 ng/dL to about 1000 ng/dL.

150. (New) The method of claim 146, wherein the second testosterone serum concentration is from about 1 to about 2 times the first testosterone serum concentration.

151. (New) The method of claim 146, wherein the third testosterone serum concentration is within about 200 ng/dL of the first testosterone serum concentration.

REMARKS

In the Office Action dated January 10, 2003, the following rejections were set forth:

a) claims 6-21 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite;

b) claims 1-21, 27, 53-55, 57-58, 60-64 and 79-145 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 18-42 of U.S. Patent No. 6,503,894;

c) claims 1-21, 27, 53-55, 57-58, 60-64 and 79-145 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 of co-pending Application No. 09/703,753; and

d) claims 1-21, 27, 53-55, 57-58, 60-64 and 79-145 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Mak *et al.* (WO 99/24041) and Heiber, *et al.* (WO 93/25168), and Omar (U.S. Patent No. 5,730,987) and Moreland *et al.* (Life Sciences 1998, 62(2), 309-318) in view of Allen (WO 96/27372).

These rejections are respectfully traversed. Upon entry of this Amendment, claims 1-21, 27, 53-55, 57-58, 60-64 and 79-151 are pending and under consideration in the present application.